Preventing future deaths from medicines

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Drug Safety

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Preventing future deaths from medicines: responses to Coroners' concerns in England and Wales

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Public access to the responses is often limited.

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Deaths from adverse drug reactions, medication errors, and the non-medicinal use of drugs are important. Although the mortality from adverse drug reactions associated with hospital admission is low in absolute terms [1], one recent Spanish study attributed 7% of all deaths in hospital wholly or partly to medicines [2], and another suggested that as many as 18% of deaths in hospital may have been related to medicines [3]. The true figures, including deaths in the community, are not well established. Deaths from medicines are therefore a significant problem, and methods to prevent them are important if patients are to be protected.

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We have previously reported findings in a consecutive series of 500 Coroners' reports posted from 24 April 2015 to 7 September 2016 [5]. Of these, 99 expressed concerns about medicines or part of the medication process or both. The cases are listed in Supplementary Table 1. Interest in these problems has increased in the last two decades: Pubmed listed 176 citations under 'medication error' in 1997, 636 in 2007, and 1114 in 2017. [6] We considered that fatal events were most likely to prompt action to increase medication safety. We wished to see what responses were made by NHS organizations and others to these 99 Coroners' reports.

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We identified the addressees named in the 99 Coroners' reports from our initial study. Where the addressee's response was posted on the UK Judiciary website [4], it was downloaded for analysis. Where the response was not published and where the addressee was identifiable, we wrote to the individual or organization concerned asking for a copy, and for NHS and other

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We examined the extent to which the responses appeared to address the concerns raised by the Coroner. We also considered the extent to which the responses were (a) of general interest and (b) generally disseminated, since errors in healthcare are recognized to be important, and lessons easily forgotten[7].

5 Results

The concerns expressed by Coroners and previously set out [5] are summarized in Table 1.

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The organizations that received Coroners' reports for the 99 cases (100 deaths) we studied are shown in Table 2. Some organizations, such as hospitals, received more than one Coroner's report and are represented more than once. The Care Quality Commission received eight different Coroners' reports, the most of any organization. A Coroner's report referred to a single inquest, but could raise more than one matter of concern.

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We identified 91 public organizations and 22 private organizations sent one or more Coroners' reports. The number of individual reports requiring a response are shown in Table 2. One Coroner's report omitted the name of the addressee, but was accompanied by a response from a hospital trust (Case 2015-0195). This was included in the figure for those required to respond and for those whose responses were posted on-line.

We identified 125 organizations that were sent a Coroners' reports but whose responses had not been published on-line at the start of our study. We in addition found one response from the Department of Health (Case 2015-0289) of the 34 responses already published was uninformative, but referred to an unpublished response from the National Medical Director of NHS England. We therefore requested information on the 126 required responses that were not in the public domain. We also requested information from a further 30 entities who were named in Coroners' reports but not required to respond. These entities included NHS England, the Care Quality Commission, and NHS Trusts that had been sent copies of reports but were not required to respond.

The numbers of requests and responses are summarized in Table 3. Details are provided in Supplementary Table 2.

The responses of 44 organizations (28% cases) to Coroners' reports were posted on the UK Judiciary website by the completion of the study [4]. We were able to analyse at least one response regarding 69/99 (70%) of the cases.

Table 3 near here please

Coroners' reports specify that an answer is to be returned within 56 days. There were 53 Coroners' reports that gave relevant dates. For these 53 reports, the median time for a Coroner to issue a report was 240 [range 73–1027] days after the date of death. The median time it took addressee organizations to respond to the Coroner's report reports was 53 [range 8–311] days.

The responses we analysed described 201 separate actions proposed or undertaken. These included: staff education or training (44/201); change in processes (24/201); and altered policies (17/201). In some cases (22/201), organizations felt existing policies were sufficient (Table 4).

Table 4 near here please

5.1 Illustrative cases

Case 2016-0096

This concerned an interaction between warfarin and miconazole oral gel (to treat the patient's oral thrush) that proved fatal. The MHRA issued advice to all relevant healthcare professionals (HCP); this message was re-iterated by the General Dental Council (GDC). The Welsh government issued a patient safety notice to all NHS organizations and independent contractor providers in Wales. The interaction warning was added to post-graduate educational material for dentists and pharmacist in Wales.

Case 2016-0143

A woman with malnutrition taking paracetamol reported abdominal discomfort. Her liver function became abnormal and, despite acetylcysteine treatment, her condition deteriorated and she died. The cause of death was given as 1a. Respiratory failure, 1b Pulmonary oedema, 1c severe multi-factorial malnutrition, 2. Acute pyelonephritis, electrolyte imbalance, anaemia, and immune deficiency. The coroner was concerned that 'the dose [of paracetamol] administered was the standard adult one', but she weighed less than 50 kg. The trust responded by citing the British National Formulary, which gave no indication that dose-adjustment was needed, and the Medicines and Healthcare products Regulatory Agency, which had stated that body-weight alone was not considered a risk for paracetamol toxicity, although malnutrition was. The trust proposed to inform prescribers of the possible need for dose reduction.

Case 2015-0414

A patient with a mechanical mitral valve was advised to avoid pregnancy, but fell pregnant. Termination was planned for 8 weeks gestation. The patient was admitted to hospital with respiratory distress. The Coroner found that 'the medical cause of death was Multi-Organ failure due to Acute Thrombosis of mechanical mitral valve in the first trimester of pregnancy…' and that inadequate doses of enoxaparin contributed to fatal thrombosis of the valve. The coroner expressed concern that pregnant women with mechanical valves may be at risk from insufficient antithrombotic therapy with enoxaparin and insufficient review of their anti-factor Xa activity. The coroner was also concerned that clinicians without specialist cardio-obstetric knowledge across the region failed to appreciate the risks of a mechanical heart valve in a pregnant patient. The British Cardiovascular Society received the Coroner's report, and responded by organising educational material and workshops on the theme of pregnancy and mechanical heart valves for its members.

Case 2015-0273

An elderly care-home patient with emphysema contracted bronchopneumonia. His GP prescribed antibiotics, which were administered. However, his regular medication was not given (aspirin, senna, doxycycline, and omeprazole). The Coroner concluded that 'death was due to bronchopneumonia as a result of emphysema, and that the omission of medicines did not cause or contribute to the patient's death, but the risk of such an omission causing death in other circumstances [was] clear.' The care home response was to establish better

communication channels with GPs in the area and obtain patient care summaries from the GP to ensure all medications are accurately managed. It has introduced medication reviews for patients and regularly updates patient care plans. The care home also reported that it now communicated with GP practices after patients were discharged from hospital to ensure any change in care or medication is implemented.

Case 2015-0423

The patient was discharged from hospital after a fall. He was supposed to receive four weeks of prophylactic low molecular weight heparin according to hospital policy and was discharged to a care home with four weeks' supply. However, documents on discharge said 3 weeks. The care home administered for three weeks. The discrepancy in the actual supply of medication, and duration in the letter was not queried, leading to sub-optimal treatment contributing to the patient's death. The cause of death was certified as '1a Pulmonary embolus; 1b Deep venous thrombosis; 1c Fractured right neck of femur; 2 Sub-optimal deep venous thrombosis prophylaxis.' The response of the care home was not published and they did not respond to our request for information. The hospital, a second addressee, did carry out a review following the death of this patient and took action intended to reduce the risk of this type of error.

Cases 2015-0463 and 2016-0014

Two cases concern fentanyl patches. In the first case, a woman with severe chronic pain had been treated by fentanyl patches for four years. The night before she died, her uncle had applied a patch, inadvertently damaged when he removed it from packaging. The coroner expressed concern to the manufacturer that there were no warnings regarding the dangers of damaged patches. The manufacturer's response is not available to us. In the second case, a woman receiving fentanyl patches as part of terminal care was told by a palliative care nurse to remove old patches by soaking in the bath; she had a hot bath and died, probably as a result of the rapid heat-induced release of remaining fentanyl from the 'spent' patch. The coroner expressed concerns to the palliative care organization, the general practice, and the manufacturer about these inadvertent overdoses. The manufacturer contacted the MHRA, who issued a warning of the potential dangers from the rapid release of fentanyl if patches are heated.

Case 2015-0229

A patient with renal disease died from codeine poisoning. The drug was prescribed at the request of a locum consultant, but neither he nor the junior doctor who wrote the prescription was aware of the relevant trust guidelines. The Trust responded that it had carried out detailed investigations and found no evidence to suggest lack of knowledge or failure of locum staff. Nonetheless, the trust decided that codeine should no longer be available for routine prescription by general surgeons.

Case 2015-0170

A patient died as a result of post-traumatic epilepsy. He was prescribed sodium valproate but was not collecting his prescriptions. His GP saw him several times but his medication was not discussed. The coroner raised concerns that general practice did not have any systems in place to monitor uncollected prescriptions. The general practice responded that it had updated its systems to alert doctors to outstanding prescriptions.

Case 2015-0377

A baby died shortly after birth following a long and complicated labour. The coroner was concerned that registrars had delayed the administration of oxytocin, indicated on clinical grounds (meconium stained liquor and infrequent contractions at late stage of labour). The coroner also raised concerns with regards to the hospitals incident review process, which did not inform or involve those responsible, and thereby missed the opportunity for the organization and the doctors to learn from the case. The organization responded that they had subsequently shared learning from this case via staff communications and amended their review process.

6 Discussion

Coroners expressed concerns about many medication errors, and directed their reports to a wide range of institutions, including prisons, hospitals, care homes, government agencies or departments, and pharmaceutical firms. In assessing the responses to these concerns, we found fewer than a third of responses published on the UK Judiciary website. There were no clear indications of what process was involved in deciding if responses were published or any indication of the timeframe in which responses would be published.

We requested from those who had received a Coroner's report any unpublished responses, using FoI legislation [8] with public bodies. 'A safety culture encourages greater transparency around errors and harm, which in turn allows for open discussions to better understand what happened—and how to prevent recurrence of the event—as well as disclosure to patients'[9]. There have been long-standing calls for openness in the NHS [10], and openness in the NHS is government policy [11]. Nonetheless, many organizations, including public bodies, were slow to respond to our requests and resisted releasing information. In the case of public bodies, this was despite repeated requests under the Freedom of Information Act. This lack of transparency hampered our study and limits the potential value of Coroners' reports.

Public health physicians in Melbourne, where all responses are published, were critical of the 'opacity of many response letters'[12]. Only 125 of 282 responses to Coroners' recommendations (44%) stated explicitly whether action had been taken or was intended.

We were unable to find any published appraisal process to show whether coroners had received responses to their reports, and whether the actions outlined in responses were appropriate.

Despite these deficiencies in the communication of medication risks and solutions, the Coroners' reports prompted actions that would otherwise probably not have been taken. Our illustrative cases show this, but also show that there may be local problems, and local solutions, that would be more useful if they were disseminated more widely. In some cases, national bodies addressed directly (cases 2016-0096, 2015-0414) or advised by others (case 2016-0014) issued warnings. In other cases, local solutions were proposed to problems of communication (case 2015-0273), monitoring (2015-0170), and timeliness of drug administration (2015-0377) that would have been of national relevance. (Table 5). Sometimes, as when codeine was banned from surgical wards to prevent prescription of the drug to patients with renal impairment (case 2015-0229), proposed solutions failed to tackle the underlying general problem that drugs are sometimes prescribed to patients in whom they are contra-indicated.

Table 5 near here please

There have been several high-profile examples of the tardy recognition of unsafe practice in the NHS, preventing lessons from being learnt quickly and so putting further lives at risk. The Independent report into deaths at the Gosport War Memorial Hospital found that poor prescribing and use of opiates led to a substantial number of premature patient deaths [13]. The inquiry found that the Coroner had not reported under 'Rule 43 of the Coroners Rules 1984: action to prevent the recurrence of similar deaths,' which preceded regulation 28 of the Coroners (Investigations) Regulations 2013 and Reports to Prevent Future Deaths. Concerns about issuing such reports arise from the perception they are punitive in nature. Coroners' reports may be more likely to contribute towards patient safety if they are directed to the relevant national organizations as well as to local addressees, but only if they are seen as an effort to achieve improvement. It is therefore important that concerns in such reports are framed constructively and are overtly conducive to patient safety.

In other jurisdictions, Coroners can make direct recommendations, rather than simply express concerns and invite recommendations [14].

For example, 'In New Zealand coroners have a duty to identify any lessons learned from the deaths referred to them that might help prevent such deaths in the future' [15]. For cases that are closed, these recommendations are published online in a searchable database [16]. A study in New Zealand retrospectively reviewed 1644 recommendations sent to one or more of 309 recipients regarding 607 coronial enquiries [17]. Of the 607 inquests, deaths caused by exposure to or poisoning by noxious substances accounted for 42, and complications of medical and surgical care for 58. Many recommendations were addressed to the Ministry of Health (134) or 'all District Health Boards' (134), and very few were sent to individuals.

An Australian study reviewed 30 medication-related deaths in residential care for the elderly. The authors identified the cases from the Australian National Coronial Information System over 14 years [18]. The medicines most often implicated were opioids and psychiatric medicines alone or together. In four cases, medicines were administered to the wrong patient. Coroners made recommendations, for example, regarding education and training. However, they did so in just three cases.

It is not currently possible to tell whether Coroners' reports save lives. Coroners are responsible for inquiring into all manner of deaths, of which deaths related to healthcare are only a part. It is not, either, the place of healthcare professionals to suggest to Coroners how

they should operate. From the perspective of the NHS, and healthcare generally, the concerns that Coroners express often bring into the open systems failures and errors of general importance. If the Coroners' reports were, as a matter of routine, addressed to the relevant national body (for example, NHS Improvement, the CQC, or the MHRA) that would ensure that higher level regulatory expertise could assess and act on any system-wide issues identified. Important information to prevent future deaths would be available to the whole NHS, and lessons less easily forgotten.

7 Conclusion

Medicines feature in a substantial number of Coroners' reports to prevent future deaths. The concerns expressed in the reports vary widely. The Coroners' reports are often addressed locally when they are of national importance, in contrast to other places such as New Zealand, where most reports are widely disseminated. In spite of pleas for openness and recognition of lessons from error improving patient safety, responses are often unpublished and many organisations are reluctant to share their responses. There appears to be no system for auditing concerns and responses to them. So it is difficult to know whether –with regards to medicines– the coronial system prevent future death. Only a minority of the responses that we have analysed appear to provide robust and generally applicable ways to prevent future deaths.

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Table 2 near here please

We identified 91 public organizations and 22 private organizations sent one or more Coroners' reports. The number of individual reports requiring a response are shown in Table 2. One Coroner's report omitted the name of the addressee, but was accompanied by a response from a hospital trust (Case 2015-0195). This was included in the figure for those required to respond and for those whose responses were posted on-line.

We identified 125 organizations that were sent a Coroners' reports but whose responses had not been published on-line at the start of our study. We in addition found one response from the Department of Health (Case 2015-0289) of the 34 responses already published was uninformative, but referred to an unpublished response from the National Medical Director of NHS England. We therefore requested information on the 126 required responses that were not in the public domain. We also requested information from a further 30 entities who were named in Coroners' reports but not required to respond. These entities included NHS England, the Care Quality Commission, and NHS Trusts that had been sent copies of reports but were not required to respond.

The numbers of requests and responses are summarized in Table 3. Details are provided in Supplementary Table 2.

The responses of 44 organizations (28% cases) to Coroners' reports were posted on the UK Judiciary website by the completion of the study [4]. We were able to analyse at least one response regarding 69/99 (70%) of the cases.

Table 3 near here please

Coroners' reports specify that an answer is to be returned within 56 days. There were 53 Coroners' reports that gave relevant dates. For these 53 reports, the median time for a Coroner to issue a report was 240 [range 73–1027] days after the date of death. The median time it took addressee organizations to respond to the Coroner's report reports was 53 [range 8–311] days.

The responses we analysed described 201 separate actions proposed or undertaken. These included: staff education or training (44/201); change in processes (24/201); and altered policies (17/201). In some cases (22/201), organizations felt existing policies were sufficient (Table 4).

Table 4 near here please

5.1 Illustrative cases

Case 2016-0096

This concerned an interaction between warfarin and miconazole oral gel (to treat the patient's oral thrush) that proved fatal. The MHRA issued advice to all relevant healthcare professionals (HCP); this message was re-iterated by the General Dental Council (GDC). The Welsh government issued a patient safety notice to all NHS organizations and independent contractor providers in Wales. The interaction warning was added to post-graduate educational material for dentists and pharmacist in Wales.

Case 2016-0143

A woman with malnutrition taking paracetamol reported abdominal discomfort. Her liver function became abnormal and, despite acetylcysteine treatment, her condition deteriorated and she died. The cause of death was given as 1a. Respiratory failure, 1b Pulmonary oedema, 1c severe multi-factorial malnutrition, 2. Acute pyelonephritis, electrolyte imbalance, anaemia, and immune deficiency. The coroner was concerned that 'the dose [of paracetamol] administered was the standard adult one', but she weighed less than 50 kg. The trust responded by citing the British National Formulary, which gave no indication that dose-adjustment was needed, and the Medicines and Healthcare products Regulatory Agency, which had stated that body-weight alone was not considered a risk for paracetamol toxicity, although malnutrition was. The trust proposed to inform prescribers of the possible need for dose reduction.

Case 2015-0414

A patient with a mechanical mitral valve was advised to avoid pregnancy, but fell pregnant. Termination was planned for 8 weeks gestation. The patient was admitted to hospital with respiratory distress. The Coroner found that 'the medical cause of death was Multi-Organ failure due to Acute Thrombosis of mechanical mitral valve in the first trimester of pregnancy…' and that inadequate doses of enoxaparin contributed to fatal thrombosis of the valve. The coroner expressed concern that pregnant women with mechanical valves may be at risk from insufficient antithrombotic therapy with enoxaparin and insufficient review of their anti-factor Xa activity. The coroner was also concerned that clinicians without specialist cardio-obstetric knowledge across the region failed to appreciate the risks of a mechanical heart valve in a pregnant patient. The British Cardiovascular Society received the Coroner's report, and responded by organising educational material and workshops on the theme of pregnancy and mechanical heart valves for its members.

Case 2015-0273

An elderly care-home patient with emphysema contracted bronchopneumonia. His GP prescribed antibiotics, which were administered. However, his regular medication was not given (aspirin, senna, doxycycline, and omeprazole). The Coroner concluded that 'death was due to bronchopneumonia as a result of emphysema, and that the omission of medicines did not cause or contribute to the patient's death, but the risk of such an omission causing death in other circumstances [was] clear.' The care home response was to establish better

communication channels with GPs in the area and obtain patient care summaries from the GP to ensure all medications are accurately managed. It has introduced medication reviews for patients and regularly updates patient care plans. The care home also reported that it now communicated with GP practices after patients were discharged from hospital to ensure any change in care or medication is implemented.

Case 2015-0423

The patient was discharged from hospital after a fall. He was supposed to receive four weeks of prophylactic low molecular weight heparin according to hospital policy and was discharged to a care home with four weeks' supply. However, documents on discharge said 3 weeks. The care home administered for three weeks. The discrepancy in the actual supply of medication, and duration in the letter was not queried, leading to sub-optimal treatment contributing to the patient's death. The cause of death was certified as '1a Pulmonary embolus; 1b Deep venous thrombosis; 1c Fractured right neck of femur; 2 Sub-optimal deep venous thrombosis prophylaxis.' The response of the care home was not published and they did not respond to our request for information. The hospital, a second addressee, did carry out a review following the death of this patient and took action intended to reduce the risk of this type of error.

Cases 2015-0463 and 2016-0014

Two cases concern fentanyl patches. In the first case, a woman with severe chronic pain had been treated by fentanyl patches for four years. The night before she died, her uncle had applied a patch, inadvertently damaged when he removed it from packaging. The coroner expressed concern to the manufacturer that there were no warnings regarding the dangers of damaged patches. The manufacturer's response is not available to us. In the second case, a woman receiving fentanyl patches as part of terminal care was told by a palliative care nurse to remove old patches by soaking in the bath; she had a hot bath and died, probably as a result of the rapid heat-induced release of remaining fentanyl from the 'spent' patch. The coroner expressed concerns to the palliative care organization, the general practice, and the manufacturer about these inadvertent overdoses. The manufacturer contacted the MHRA, who issued a warning of the potential dangers from the rapid release of fentanyl if patches are heated.

Case 2015-0229

A patient with renal disease died from codeine poisoning. The drug was prescribed at the request of a locum consultant, but neither he nor the junior doctor who wrote the prescription was aware of the relevant trust guidelines. The Trust responded that it had carried out detailed investigations and found no evidence to suggest lack of knowledge or failure of locum staff. Nonetheless, the trust decided that codeine should no longer be available for routine prescription by general surgeons.

Case 2015-0170

A patient died as a result of post-traumatic epilepsy. He was prescribed sodium valproate but was not collecting his prescriptions. His GP saw him several times but his medication was not discussed. The coroner raised concerns that general practice did not have any systems in place to monitor uncollected prescriptions. The general practice responded that it had updated its systems to alert doctors to outstanding prescriptions.

Case 2015-0377

A baby died shortly after birth following a long and complicated labour. The coroner was concerned that registrars had delayed the administration of oxytocin, indicated on clinical grounds (meconium stained liquor and infrequent contractions at late stage of labour). The coroner also raised concerns with regards to the hospitals incident review process, which did not inform or involve those responsible, and thereby missed the opportunity for the organization and the doctors to learn from the case. The organization responded that they had subsequently shared learning from this case via staff communications and amended their review process.

6 Discussion

Coroners expressed concerns about many medication errors, and directed their reports to a wide range of institutions, including prisons, hospitals, care homes, government agencies or departments, and pharmaceutical firms. In assessing the responses to these concerns, we found fewer than a third of responses published on the UK Judiciary website. There were no clear indications of what process was involved in deciding if responses were published or any indication of the timeframe in which responses would be published.

We requested from those who had received a Coroner's report any unpublished responses, using FoI legislation [8] with public bodies. 'A safety culture encourages greater transparency around errors and harm, which in turn allows for open discussions to better understand what happened—and how to prevent recurrence of the event—as well as disclosure to patients'[9]. There have been long-standing calls for openness in the NHS [10], and openness in the NHS is government policy [11]. Nonetheless, many organizations, including public bodies, were slow to respond to our requests and resisted releasing information. In the case of public bodies, this was despite repeated requests under the Freedom of Information Act. This lack of transparency hampered our study and limits the potential value of Coroners' reports.

Public health physicians in Melbourne, where all responses are published, were critical of the 'opacity of many response letters'[12]. Only 125 of 282 responses to Coroners' recommendations (44%) stated explicitly whether action had been taken or was intended.

We were unable to find any published appraisal process to show whether coroners had received responses to their reports, and whether the actions outlined in responses were appropriate.

Despite these deficiencies in the communication of medication risks and solutions, the Coroners' reports prompted actions that would otherwise probably not have been taken. Our illustrative cases show this, but also show that there may be local problems, and local solutions, that would be more useful if they were disseminated more widely. In some cases, national bodies addressed directly (cases 2016-0096, 2015-0414) or advised by others (case 2016-0014) issued warnings. In other cases, local solutions were proposed to problems of communication (case 2015-0273), monitoring (2015-0170), and timeliness of drug administration (2015-0377) that would have been of national relevance. (Table 5). Sometimes, as when codeine was banned from surgical wards to prevent prescription of the drug to patients with renal impairment (case 2015-0229), proposed solutions failed to tackle the underlying general problem that drugs are sometimes prescribed to patients in whom they are contra-indicated.

Table 5 near here please

There have been several high-profile examples of the tardy recognition of unsafe practice in the NHS, preventing lessons from being learnt quickly and so putting further lives at risk. The Independent report into deaths at the Gosport War Memorial Hospital found that poor prescribing and use of opiates led to a substantial number of premature patient deaths [13]. The inquiry found that the Coroner had not reported under 'Rule 43 of the Coroners Rules 1984: action to prevent the recurrence of similar deaths,' which preceded regulation 28 of the Coroners (Investigations) Regulations 2013 and Reports to Prevent Future Deaths. Concerns about issuing such reports arise from the perception they are punitive in nature. Coroners' reports may be more likely to contribute towards patient safety if they are directed to the relevant national organizations as well as to local addressees, but only if they are seen as an effort to achieve improvement. It is therefore important that concerns in such reports are framed constructively and are overtly conducive to patient safety.

In other jurisdictions, Coroners can make direct recommendations, rather than simply express concerns and invite recommendations [14].

For example, 'In New Zealand coroners have a duty to identify any lessons learned from the deaths referred to them that might help prevent such deaths in the future' [15]. For cases that are closed, these recommendations are published online in a searchable database [16]. A study in New Zealand retrospectively reviewed 1644 recommendations sent to one or more of 309 recipients regarding 607 coronial enquiries [17]. Of the 607 inquests, deaths caused by exposure to or poisoning by noxious substances accounted for 42, and complications of medical and surgical care for 58. Many recommendations were addressed to the Ministry of Health (134) or 'all District Health Boards' (134), and very few were sent to individuals.

An Australian study reviewed 30 medication-related deaths in residential care for the elderly. The authors identified the cases from the Australian National Coronial Information System over 14 years [18]. The medicines most often implicated were opioids and psychiatric medicines alone or together. In four cases, medicines were administered to the wrong patient. Coroners made recommendations, for example, regarding education and training. However, they did so in just three cases.

It is not currently possible to tell whether Coroners' reports save lives. Coroners are responsible for inquiring into all manner of deaths, of which deaths related to healthcare are only a part. It is not, either, the place of healthcare professionals to suggest to Coroners how

they should operate. From the perspective of the NHS, and healthcare generally, the concerns that Coroners express often bring into the open systems failures and errors of general importance. If the Coroners' reports were, as a matter of routine, addressed to the relevant national body (for example, NHS Improvement, the CQC, or the MHRA) that would ensure that higher level regulatory expertise could assess and act on any system-wide issues identified. Important information to prevent future deaths would be available to the whole NHS, and lessons less easily forgotten.

7 Conclusion

Medicines feature in a substantial number of Coroners' reports to prevent future deaths. The concerns expressed in the reports vary widely. The Coroners' reports are often addressed locally when they are of national importance, in contrast to other places such as New Zealand, where most reports are widely disseminated. In spite of pleas for openness and recognition of lessons from error improving patient safety, responses are often unpublished and many organisations are reluctant to share their responses. There appears to be no system for auditing concerns and responses to them. So it is difficult to know whether –with regards to medicines– the coronial system prevent future death. Only a minority of the responses that we have analysed appear to provide robust and generally applicable ways to prevent future deaths.

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Table 1. Concerns expressed by Coroners in 99 reports to prevent future deaths regarding 100 deaths [5].

Concern	**No. of occurrences**
ADR to prescribed medicines	22
Omission of necessary treatment	21
Monitoring failure	17
Poor systems	17
Poor communication	13
Drug regulation inadequate (or failure to enforce)	9
Interaction	7
Contra-indicated	5
Failure of training	5
Susceptible patient	5
Delayed treatment	4
Failure to appreciate risk (of recurrent or continued symptoms)	4
Failure to warn of adverse drug reactions	4
Excessive supply	3
Failure to adjust dose	3
Poor medicines control (in prison)	3
Failure to follow protocol	2
Failure to take history or see patient	2
Inadequate training	2
Inappropriate dose for patient	2
Poor training	2
Effect of medication hindered diagnosis	1
Failure to follow recommended practice	1
Failure to investigate whether excessive dose was given	1
Failure to review medicines	1
Inadequate diagnosis before prescribing	1
Manufacturing fault in slow-release patch	1
Poor awareness of rare ADRs	1
Should have been avoided	1
Total	160

Table 2. The distribution of addressee organizations by type for 99 Coroners' reports concerning 100 deaths related to medicines

Organisation type group	Required to respond to PFD	Response after FoI	Response online by the end of the study	Total number of responses made public	%
Care Homes	6	1	1	2	33%
NHS hospitals, Trusts and CCGs†	79	39	20	59	76%
Private companies*	12	4	2	6	50%
Individual ministers/Government agencies or department	19	6	7	12	63%
GP surgeries and medical centres	12	6	5	11	92%
Prison	6	1	3	4	67%
Police and emergency services	4	1	1	2	50%
Regulatory bodies and trade associations*	20	4	5	9	45%
Local authorities	1	1	0	1	100%
Total	159	63	44	107	67%

†Includes one Coroner's report that did not state any addressee, but to which an NHS Trust responded

*Private entities are not subject to FoI legislation. We requested information from them.

NHS = national health service; CCG = Clinical commissioning group; GP = General practitioner; FoI = Freedom of Information; PFD = Coroner's report to Prevent Future Deaths

Table 3. Responses of organizations to our request for information regarding Coroners' reports in 99 cases (100 deaths).

Number of entities required to respond to Coroners' concerns	Number of responses posted on-line at the start of the study	Number of addressees required to respond who were sent FoIs	Total number sent FoIs or requests for data	Number who provided data in response to request	Number who responded but did not provide data	Number who failed to respond
159	34	126	156*	73	58	25

*30 requests were sent to organizations named in Coroners' reports but not required by law to respond; one request was sent to an organization whose on-line response contained no relevant information

Table 4. Broad categories of response to Coroners' concerns. Many addressees proposed more than one action in response to a single concern.

Action type	**number of instances**
A. Doing things better (improving systems or processes, better monitoring, increasing staffing level)	44
(Including Change in process	24)
B. Looking to see if you can do things better (root cause analysis, review, new audit)	32
C. Teaching or advising people to do things better (education & training, warnings, new label)	62
(Including Staff education or training	44)
D. Saying you will do things better (new policies or amended policies, new laws)	30
(Including Change in policy	17)
E. Doing nothing or prevaricating (existing policies are sufficient, no action taken, further action under consideration)	33
(Including Existing policies sufficient	22)
Grand Total	**201**

The details of each case are in the supplementary information 'Categories of concern'.

Table 5: Relevance and dissemination of each concern expressed in the 69 Coroners' reports for which responses were available.

Wide Relevance / Widely Disseminated	No	Unclear	Yes	Total
No	2	5	37	44
Partly	0	0	1	1
Yes	0	1	23	24
Total	2	6	61	69

Preventing future deaths from medicines: responses to Coroners' concerns in England and Wales. Drug Safety. Robin E Ferner, Tohfa J Ahmad, Zainab Babatunde, Anthony R Cox. Corresponding author Robin E Ferner, Email: r.e.ferner@bham.ac.uk

Supplementary Table 1. Cases in which coroners made reports to prevent future deaths in which they expressed concerns about medicines or the medication process that contributed to death, out of a total of 500 reports published between 24th April 2015 to 7th September 2016.

	Age & sex	Case report no.	To	Drug	Classification(s)	Error	Type
1.	90 F	2016-0071	Managing director Cuerden Care Homes	Low molecular weight heparin (dalteparin)	Anticoagulants	Extra five injections given; not causative. Care Home medication not sufficiently controlled – bad policies	Excessive supply (unprescribed)
2.	63 M	2016-0183	Chief Executive Officer Blackburn	Lamotrigine Sodium valproate		Omitted while undergoing surgery	Omission of necessary treatment
3.	43 M	2015-0451	Medical Director Manchester NHS Area Team	Amisulpride	Psychiatric	Failure to prescribe; poor electronic communication; failure to notice omission of treatment; schizophrenia; hanged	Omission of necessary treatment
4.	M	2015-0229	Chief Executive, Brighton Chief Nurse, Brighton Ward Manger, Brighton	Codeine – four doses in 18 h	Opioids	Bipolar; fall; stage 4 kidney failure; pneumothorax; poisoned by codeine prescribed by locum; partial response to naloxone; breached local and national policy	Contra-indicated

5.	M	2015-003811	Chief Executive Officer Cambrian Group Chief Executive, Guys & St Thomas	Zopiclone + lorazepam	Hypnotics and sedatives	Obstructive sleep apnoea; severe obesity; defective CPAP machine; poor observations; failure to communicate risk to psychiatrists	Contra-indicated
6.	25 F	2015-0413	Chief Executive, Cheltenham Head of Legal Services, Cheltenham	Low molecular weight heparin Anticoagulant	Anticoagulants	Severe chest pain; anticoagulated; but pain was from splenic artery aneurysm rupture. Senior clinicians not involved;	Inadequate diagnosis before ℞
7.	43 M	2016-0238	Spectrum Community Health National Offender Management Service G4S	Medication for depression and anxiety	Psychiatric	Hanged; did not have prescribed treatment; awaiting review by GP; health professionals not involved in ACCT [Assessment, Care in Custody, Teamwork]. Clear need for training.	Omission of necessary treatment
8.	30 F	2016-0208	A GP practice North, East & West Devon Clinical Commissioning Group	Paracetamol Pregabalin		Not prescribed. Down syndrome with learning difficulties. Mother-in-law's pregabalin. Overdose.	Poor medicines control Susceptible patient (vulnerable adult)
9.	M	2015-0394	Director, National Probation Service	Heroin	Opioids	The lack of forward planning for his release from prison increased the risk of him using heroin. Discharged to Hostel, where he took heroin: in	Monitoring failure

						bathroom for 4 h before being found collapsed.	
10.	M	2015-0468	Director Birmingham Prison National Offender Management Service Birmingham, Prisons Minister Birmingham Community HealthCare NHS Trust	Methadone Buprenorphine Diazepam Quetiapine Pregabalin Gabapentin Hyoscine 5f-AKB48 (cannabinoid)	Opioids Psychiatric Drug of Abuse Hypnotics and sedatives	He self-administered various medication - non-prescribed substance and legal highs – gained by exploiting inadequacies within the prison; post-mortem toxicology showed many drugs present. A cell search also found many drugs. Problems with screening visitors, checking prisoners, and so on.	Poor medicines control
11.	M	2015-0255	Chief Executive University Hospitals Leicester Chief Executive NHS England Chief Executive East Midlands Ambulance service	Low molecular weight heparin (dalteparin)	Anticoagulants	Stroke; delay in hospital transfer; given usual daily dose of dalteparin	Contra-indicated
12.	85 M	2015-0301	Chief Executive, Northern General Sheffield & Cardiothoracic unit	Amiodarone		No protocol for monitoring amiodarone in General Practice	Monitoring failure
13.	25 F	2015-0438	Head of Serious Incidents, Policy &	Sertraline	Psychiatric	Hanged; dose of sertraline increased; failure to	Failure to warn of ADRs

			Patient Safety Directorate, Basildon			communicate; dose of sertraline again increased; no proper medication history on assessment; risks of sertraline not communicated; prescribing without seeing the patients.	Failure to take history or see patient
14.	18 M	2016-0013	Chief Executive, Great Western Hospital	Corticosteroids		Congenital adrenal hyperplasia; corticosteroid omitted after admission	Omission of necessary treatment (Withdrawal of corticosteroids)
15.	32 F	2015-0463	Teva Pharma	Fentanyl	Opioids	Accidental overdose of prescribed medication. A damaged patch released excess fentanyl	Manufacturing fault in slow-release patch
16.	80 F	2015-0196	A GP Practice Director City & Hackney GP Confederation	Asthma pump		Treated for asthma, but had heart failure; Out-of-hours service misled by prescribed medicines	Poor communication
17.	M	2016-0147	Sandwell & West Birmingham NHS Trust University Hospitals Birmingham NHS Trust	Warfarin	Anticoagulants	Fall, brain bleed, but slow to give human prothrombin complex (Beriplex®). Aortic valve replacement	Delayed treatment
18.	50 M	2015-0170	Senior Partner, Springfield Medical Practice	Sodium valproate		Post traumatic epilepsy; seen at surgery but no enquiry regarding failure to obtain a prescription for required meds; no system to	Omission of necessary treatment; Poor systems

						highlight patients who fail to obtain necessary treatment	(regarding repeat prescribing)
19.	68 F	2015-04041	Chief Executive, Royal Bolton Hospital	Lorazepam	Hypnotics and sedatives	Family allege that twice the recommended dose given; chart did not record this; not causal	Failure to investigate whether excessive dose was given
20.	16 F	2016-0222	Chief Executive, Walsall	Diclofenac		Recognised ADR: bleeding; poor transmission of information; failure to consider drug cause	ADR to prescribed medicines (not considered)
21.	36 F	2016-0143	Rotherham Hospital	Paracetamol		Severe malnutrition; standard dose of paracetamol given; but Mrs C weighted less than 50 kg; deranged blood tests of liver function	Inappropriate dose for patient
22.	36 M	2016-0239	Chief Executive, Wallich Centre Another	Drug of abuse	Drug of Abuse	Hostel for the homeless. Found in lavatory with needle in groin. Helped to bed by fellow resident. Found dead next morning. Staff had no training or guidance.	Failure of training Monitoring failure (after overdose)
23.	50 F	2015-0410	Chief Executive, Nottinghamshire Healthcare NHS Trust	Opiates Quetiapine	Opioids Psychiatric	Overdose after home leave. Assessed as at high risk. Given home leave the next day. Took fatal overdose.	Failure of training Failure to appreciate risk (of further overdose)
24.	86 F	2015-0402	Senior Partner, Alexander House Health Centre, Wigan	Rivaroxiban Clopidogrel	Anticoagulants	Intracerebral haemorrhage while on dual therapy for two different conditions: transient ischaemic attacks and atrial fibrillation. Also amyloid angiopathy.	Interaction ADR to prescribed medicines Should have been avoided (NICE)

25.	25 M	2016-0058	Chief Executive, Nottinghamshire Healthcare NHS Trust Medical Director CRI Locality director for Nottinghamshire area Team	Diamorphine	Opioids	Long history of substance abuse. Overdose. Psychiatrist's assessment. Delay in appointments. A period of abstinence. A benefits pay-out. Heroin overdose caused death	Monitoring Failure Failure to warn (of OD risk after abstinence)
26.	29 days, F	2015-0289	Department of Health	Pertussis vaccine		Contrary to guidance, was not offered pertussis vaccine	Omission of necessary treatment Poor systems (No way of ensuring vaccination)
27.	83 F	2016-0252	Chief Executive Western Sussex Hospitals South East Coast Ambulance Service Integrated Care 24 Ltd	Apixaban	Anticoagulants	Hip fracture; nose bleed; called NHS 111; massive GI bleed; patient not given details of ADRs	ADR to prescribed medicines; poor communication
28.	M	2015-0273	Directors of Springfield Care Home	Doxycycline	Antibiotics	Chest infection; GP prescribed antibiotics; home had	Omission of necessary treatment

						inadequate records; doxycycline omitted	Poor systems (records inadequate)
29.	M	2016-0173	Governor, HMP Gartree Acting Chief Executive, E Midlands Ambulance Service	Prescribed and non-prescribed drugs		Plastic bag + overdose. Asphyxia and multidrug toxicity caused death—poor care. Took prescribed and non-prescribed drugs that he should not have had in his possession	Poor medicines control (in prison) Poor systems
30.	37 F	2015-0372	Home Secretary Minister of State for Crime Prevention Advisory Council on Misuse of Drugs	Methoxy-phenidine Cocaine	Drug of Abuse	Methoxyphenidine [was] not a controlled drug	Drug regulation inadequate
31.	M	2015-0453	National Offender Management Service G4S	Unknown		Drugs hidden in body cavity. Observed to be under the influence of drugs. No assessment. Lack of appreciation of risk.	Failure of training Monitoring failure (after overdose)
32.	F	2016-0117	Acting Medical Director, Barts	Morphine sulfate Dihydrocodeine Paracetamol	Opioids	Perforated caecum; caesarean; Ogilvie's syndrome [colonic dilation]; several obstetric registrars were aware that the CT scan revealed a large volume in the peritoneum, but did not then seek a surgical consult	Effect of medication hindered diagnosis

33.	49 M	2016-0057	Chief Executive, Bolton Hospital	Antianginals		A&E does not stock; pharmacy prescription; pharmacy closed; therefore, patient did not get treatment	Poor systems (difficult to supply potentially life-saving treatment)
34.	M	2015-0264	Chief Executive, Maudsley Trust	Olanzapine	Psychiatric	Maudsley failed to address the risk of developing diabetes from the long-term use of olanzapine	Monitoring failure
35.	F	2016-0078	Chief Executive, Pennine Care NHS Foundation Trust Director of Commissioning/Hea d for Mental Health, Rochdale, Hayward and Middleton CCG	Unstated		Taken to emergency department acutely anxious and planning to jump off a viaduct: she subsequently ingested an excessive quantity of prescribed medication, with fatal consequences. The 'Discharge Pad' identified that the deceased was feeling suicidal and showed that the friend who collected her had expressed concern that Susan may take all her medication at once	Poor medicines control
36.	89 F	2015-0419	Alexandra Court Care Home	Treatment for myasthenia gravis		Not receiving prescribed medication that she required to control the potentially life-threatening condition myasthenia gravis.	Omission of necessary treatment; Poor systems (no medicines reconciliation)
37.	M	2016-0248	Alexandra Court Care Home	Warfarin	Anticoagulants	Falls, chronic subdural GP was not aware he was on warfarin ADR and contraindication	ADR to prescribed treatment Susceptible patient (falls)

38.	M	2015-0192	Advisory Council on Misuse of Drugs	Acetylfentanyl	Opioids	He was known to abuse drugs and drugs paraphernalia was found in the room with him. This drug is being marketed legally and is available over the internet.	Drug regulation inadequate [or failure to enforce]
39.	86 F	2015-0161	Minister of Health for Wales Chief Executive, Cwm Taf University Health Board	Warfarin Colchicine Allopurinol	Anticoagulants	Started on colchicine and allopurinol; insufficient monitoring; cerebral infarction and haemorrhage	Interaction → ADR Monitoring failure
40.	70 M	2016-0115	Chief Executive, Medway NHS Foundation Trust	Teicoplanin	Antibiotics	Failure to obtain history of MRSA. Error in recording MRSA status Prophylaxis omitted in patient with MRSA	Omission of necessary treatment
41.	M	2016-0131	Chief Executive North East London Foundation Trust Chief Officer, Redbridge CCG	Citalopram, tramadol, mirtazapine	Opioid Psychiatric	Despite history of overdoses, his access to medicines was not limited. Overdose by ingesting excessive amounts of medicines	Excessive supply
42.	84 M	2015-0317	National Patient Safety Agency Chief Fire Officer Staffordshire	Cetraben emollient cream		Burned to death	ADR to prescribed medicines Susceptible patient (smoker)

			Chief Fire Officers Association				
43.	'elderly' F	2016-0047	Chief Executive, West Wales General Hospital Glangwili Carmarthen	Low molecular weight heparin (Tinzaparin)	Anticoagulants	Breakdown of a left gluteal haematoma caused by tinzaparin therapy. Failure of monitoring creatinine or effect	Monitoring failure Failure to adjust dose
44.	F	2015-0254	Chief Executive, East Kent Hospital	Anticoagulant therapy	Anticoagulants	Multiple rib fractures. INR 6. Haemothorax. Death	ADR to prescribed medicines
45.	M	2016-0163	Director of Commissioning, NHS England, Central Midlands President Chief Fire Officers Chief Executive Reckitt Benckiser.	E45 emollient cream		Burned to death	ADR to prescribed medicines Susceptible patient (smoker)
46.	50 F	2015-0392	New Court Surgery	Citalopram	Psychiatric	Depressed. Hanged. Citalopram for 5½ years without review	Monitoring failure
47.	66 F	2015-0195	Omitted	Antibiotics	Antibiotics	Necrotizing fasciitis post op; inadequate antibiotic therapy	Omission of necessary treatment
48.	83 F	2015-0221	Betsi Cadwaladr University Health Board	Risperidone	Psychiatric	Failure to review medication; falls' fracture femur. Death	Failure to review medication ADR to prescribed medicines
49.	58 M	2016-0228	Chief Executive, Stockport NHS Trust	Enoxaparin	Anticoagulants	Deep vein thrombosis after fracture tibia and fibula.	Inappropriate dose for patient

						Weighed 99.8 kg. Given dose of 40 mg. Accurate weight is essential	
50.	:50 F	2016-0111	Chesterfield Royal Hospital	Potassium chloride		Prolonged QT interval, ventricular tachycardia, hypokalaemia 2.4 mmol/L, alcoholic liver disease	Monitoring failure Failure to follow protocol Omission of necessary treatment
51.	1 day M	2015-0377	Medical Director, Whittington Hospital	Oxytocin		Meconium stained liquor. Delay in starting Syntocinon® infusion, which should have been started 4½ hours before. Baby died.	Delayed treatment Poor training
52.	F	2015-0414	University Hospital Birmingham Birmingham Women's NHS Foundation Trust	Low molecular weight heparin (Enoxaparin)	Anticoagulants	Mechanical mitral valve; advised to avoid pregnancy; problem with valve; thrombosis of prosthetic valve; failure of hospital clinicians to prescribe adequate doses of enoxaparin contributed to the fatal thrombosis	Omission of necessary treatment
53.	20 M	2015-0191 J	Home secretary	MDMA	Drug of Abuse	MDMA – Drug of Abuse only (both brothers) obtained via Dark Web	Drug regulation inadequate
	19 M	2015-0191 T	Home secretary	MDMA	Drug of Abuse	MDMA – Drug of Abuse only (both brothers) obtained via Dark Web	Drug regulation inadequate
54.	25 F	2015-0217	Department of Health	eCigarette fluid	Drug of Abuse	Ingestion of one bottle → multiple organ dysfunction → death	Drug regulation inadequate

55.	M	2015-0282	Chief Executive University Hospital of Wales Consultant Geriatrician	Morphine	Opioids	Failure to inform GP of inadvertent overdose; inadequate systems to inform GP	Poor communication Poor systems (failure to warn of potential ADR)
56.	63 F	2016-0174	North Middx Hospital	Clozapine	Psychiatric	ADR → myocarditis [Monitoring failure when admitted] Recommendation not related to ADR, but ADR → death	ADR to prescribed medicines
57.	83 F	2016-0062	Chief Executive Officer, East Lancashire Healthcare	Low molecular weight heparin	Anticoagulants	Fracture of left leg and ankle. ℞ LMWH stopped at discharge. Deep venous thrombosis, pulmonary embolus, death	Omission of necessary treatment
58.	18 M	2016-0254	Cambridge and Peterborough NHS Foundation Trust A GP Practice CCG NHS England	Antidepressant	Psychiatric	Seen by a nurse, who recommended an antidepressant GP prescribed anti-depressant without seeing patient Walked in front of a train	Failure to warn of ADRs Failure to take history or see patient Poor communication
59.	78 M	2015-0247	Chief Executive, Royal Devon & Exeter	Flucloxacillin	Antibiotics	Developed cholestatic jaundice with flucloxacillin. Discharged without notifying GP of this. GP Practice nurse prescribed flucloxacillin again, provoking a fatal reaction	Poor communication Failure to warn of ADRs

60.	80 F	2016-0156	Manager, Acorn Lodge Care Home	Oxygen		It had been reported that the patient had been lying supine on the bed saturating at 84% and struggling to breath. The oxygen could not be heard to be running and it was noted that only 1 litre was running when this should have been a15 litre flow with the mask applied.	Omission of necessary treatment Poor training
61.	85 M	2016-0171	Chief Executive, South Manchester University Hospital Trust	Antibiotics	Antibiotics	Discharged from hospital without antibiotics or a discharge letter	Omission of necessary treatment Poor communication
62.	M	2015-0237	Chief Constable of Surrey	Cocaine Amphetamine Butylone	Drug of Abuse	Arrested. Taken in a police van. Died. Incomplete information provided to arresting officers. Especially that he had previously swallowed class A drugs. Drug-related death.	Poor communication Failure of training
63.	36 M	2015-0231	Director of Pharmacovigilance, MHRA	Cocaine Citalopram	Psychiatric Drug of Abuse	Blood contained cocaine, citalopram, methadone, heroin Subarachnoid haemorrhage after cocaine while taking citalopram The drugs led to death	Interaction
64.	M	2016-0295	Advisory Council on Misuse of Drugs	Pentobarbital		Self-administered; kept in the veterinary practice where deceased worked; it is abused.	Drug regulation inadequate

						It is only a Schedule 3 drug, not Schedule 2.	
65.	48 M	2016-0010	Minister for Policing, Fire, and Criminal Justice DVLA Medical Branch Chief Medical Advisor	Alcohol Synthetic cannabinoid	Drug of Abuse	Hanging in prison. Had taken legal highs (5F AKB-48, 5F PB-22)	Drug regulation inadequate
66.	93 F	2015-0310	Minister of Health Wales Chief Executive NHS Wales	Levothyroxine		Failure to record regular medication on admission; absence of medicines reconciliation policy; thyroxine omitted for five weeks	Omission of necessary treatment Poor systems (No medicines reconciliation)
67.	34 M	2016-0224	Governor, HMP Rochester	Anabolic steroid	Drug of Abuse	Anabolic-steroid induced cardiomyopathy; ventricular tachycardia, probable pulmonary embolism. Death in prison.	Delayed treatment Failure to follow protocol Inadequate training
68.	1 day M	2015-0177	Department of Health; Royal College of Obstetrics NICE Royal College of Paediatrics	Antibiotics	Antibiotics	Group B streptococcus in previous pregnancy; no prophylactic antibiotics. Baby died from Group B strep	Omission of necessary treatment
69.	34 M	2015-0444	Worcestershire Health and Care	Propranolol Citalopram	Psychiatric	Asthma; had previously had propranolol. This was contra-	Contra-indicated

				Olanzapine Amitriptyline		indicated, but not noted to be contra-indicated in the medical records. While attempts had been made to stop it, it had been reintroduced	Monitoring failure (ECG)
70.	74 M	2015-0400	Chief Executive, Cardiff and Vale University Health Board	Noradrenaline		Intensive care after major bladder surgery, noradrenaline line inadvertently disconnected. Failure to label IV lines. No protocol for this.	Omission of necessary treatment Poor systems (Lines not labelled)
71.	74 F	2016-0014	Churchgate Surgery; Macmillan Cancer Care; Takeda	Fentanyl patch	Opioids	Took a hot bath while wearing a fentanyl patch; died. Death was caused by fentanyl toxicity. Patient Leaflet warns on page 8 of 'prolonged hot bath,' but these terms are not defined	Failure to warn of ADRs
72.	64 M	2016-0246	Doncaster Royal Infirmary	Fluticasone (in Seretide®)		Pneumonia in a man with lung cancer. Inhaled fluticasone lowered his immunity. Coroner determined that fluticasone is not useful if the eosinophil count is not raised	ADR to prescribed medicines
73.	56 F	2015-0295	Director of Pharmacovigilance, MHRA Director CCP, NICE	Lisinopril Spironolactone		Chronic kidney disease, Type 2 DM, fibromyalgia, heart failure. Twenty-two different medicines. Non-prescribing nurse printed a prescription, then GP signed Hyperkalaemia 9.7 mmol/L → death	Interaction Poor systems (non-prescriber decided prescription)

			Medical Director, Lincolnshire Community Health Service				
74.	54 M	2015-0210	Secretary of State for Health Chief Executive Officer, University Hospital South Manchester	Warfarin	Anticoagulants	Failed to attend anticoagulant clinic on three occasions; lack of a system for repeat prescribing.	Poor systems (for repeat prescribing)
75.	77 F	2015-0423	Chief Executive, HC-One [Care Homes]	Low molecular weight heparin (dalteparin)	Anticoagulants	Fractured neck of femur. Policy is to give prophylactic low molecular weight heparin for 4 weeks; documents on discharge said 3 weeks; 'notes inaccurate.'	Poor communication (wrong information)
76.	60 F	2016-0197	Chief Executive, East Lancashire Healthcare NHS Trust	Pharmacological thrombo-prophylaxis	Anticoagulants	Fracture left arm and leg; not given appropriate prophylaxis; deep; vein thrombosis, death. Failure to follow Trust protocol	Omission of necessary treatment Poor systems (Failure to follow protocol; e-prescribing did not extent to the emergency department)
77.	95 F	2015-0241	Chief Executive, Heart of England NHS Foundation Trust	Low molecular weight heparin (enoxaparin) and aspirin	Anticoagulants	Atrial fibrillation, congestive heart failure, chronic kidney disease. Bled from duodenal ulcers. Cirrhosis.	ADR to prescribed medicines Interaction

						Electronic discharge letter and written prescription differed	
78.	23 M	2015-0474	Medical Director, Greater Manchester NHS Area Team Chief Executive, Greater Manchester West Mental Health NHS Foundation Trust Bodmin Road Health Centre	Benzodiazepine (diazepam)	Hypnotics and sedatives	Hanging; illicit drugs (benzos) and legal highs found. Confusion over benzodiazepine dose reduction. Phoenix Futures (addiction support service) cannot prescribe	Poor communication
79.	M	2016-0017	Chief Executive, Stockport NHS Foundation Trust	Insulin levemir		Accidentally omitted Died of diabetic keto-acidosis	Omission of necessary treatment
80.		2016-0242	Chief Executive. Central Manchester University Hosp NHS Foundation Trust	Co-amoxiclav	Antibiotics	Given prophylactically Known to have penicillin allergy by GP letter; co-amoxiclav contains a penicillin. Patient given co-amoxiclav, developed toxic epidermal necrolysis, and died.	Contra-indication ADR to prescribed medicines
81.	94 M	2016-0075	Chief Executive, Barts Health	Opiates (morphine sulfate, codeine, fentanyl via epidural)	Opioids	Fall at home. Dynamic hip screw; pain managed with opiates; gradually increasing opiate toxicity led to aspiration pneumonia and death	ADR to prescribed medicines Failure to adjust dose Susceptible patient

82.	35 M	2015-0298	Dorset Healthcare University NHS Foundation Trust HMP Exeter	Methadone	Opioids	Known abuser of heroin, amphetamine, diazepam, cannabis. No drugs for weeks before admission. Risk of self-harm. Under 30–60 minute observation. Given medication for 'seizures and detoxification; dead in the morning	ADR to prescribed medicines Monitoring failure Poor systems Poor Communication
83.	32 M	2015-0382	Governor, HMP Hewell Worcestershire Health & Care Trust	Methadone Mirtazapine Olanzapine Zopiclone	Opioids Psychiatric Hypnotics and sedatives	Known high risk drug taker who took prescribed and other medicines in his cell. Death in prison	Failure to appreciate risk (of illicit drug-taking) Poor communication Monitoring failure
84.	29 M	2016-0042	Secretary of State for Health	Acetylfentanyl	Opioids	'Legal high'	Drug regulation inadequate
85.	F	2015-0199	Chief Executive, Surrey & Sussex Healthcare Chief Executive, Surrey & Borders Partnership	30 sleeping tablets		Overdose. But Coroner's concern was the misunderstandings arising from untrained staff as interpreters; and poor assessment	Poor communication (unqualified interpreter) Inadequate training Failure to appreciate risk
86.	45 F	2016-0123	Chief Executive, MHRA	Opiates Morphine Tramadol	Opioids Psychiatric	Escalating dose of oral morphine: 100 → 280 → 500 ml	ADR to prescribed medicines

				Pregabalin Mirtazapine		Morphine 10 mg/5 ml is not subject to constraints (Schedule 5 of the Misuse of Drugs Act.) Then died. 500 ml could be issued without control	Failure to adjust dose Drug regulation inadequate
87.	36 M	2016-0081	A GP Practice	Mirtazapine Pregabalin	Psychiatric	Hanged; treatment was stopped by doctors at acute hospital pending review; not reviewed before his suicide. Concern: the effectiveness of existing office systems and procedures in relation to the receipt of discharge summaries from hospitals which advise on the review of patient's medication.	Poor systems (advice on review of medication)
88.	17 M	2016-0176	Medical Director, East London NHS Foundation Trust	Cannabis MDMA	Drug of Abuse	Taken to hospital with a drug related psychotic episode after having taken cannabis and ecstasy at a music festival. Assessed. Discharged with no plan. Deteriorated. Police officers saw him running towards a river. One gave chase. Jack jumped in the river and drowned.	Poor communication Failure to appreciate risk (of recurrent or continued symptoms) Poor systems

89.	79 F	2016-0096	General Dental Council British Medical Association Royal Pharmaceutical Society Royal College of GPs NHS England, Wales, Scotland	Warfarin Miconazole gel	Anticoagulants Antibiotics	Atrial fibrillation on warfarin Two weeks before admission: miconazole gel for oral thrush Intracerebral haemorrhage INR (clotting test) > 10 [Therapeutic 2.5]. Died	Interaction: ADR to prescribed medicines
90.	36 M	T2015-0309	Chief Executive, Norfolk & Suffolk NHS Foundation Trust	Medication for psychiatric disease	Psychiatric	Medication changed. Psychiatrist warned of the need to monitor. Care coordinator did not know what to look for.	Monitoring failure Poor communication Failure of training
91.	86 M	2016-0079	Chief Executive, Royal Pharmaceutical Society Chief Executive, Dispensing Doctors' Association	Finasteride		Finasteride comes in a blister pack. Snipped and placed in MCCA. Deceased swallowed a tablet still in its blister pack. It perforated the gut and he died. Professional bodies advise against this.	Failure to follow recommended practice
92.	M	2015-0262	Minister for Health, Wales	Warfarin	Anticoagulants	Warfarin for metallic heart valve Missed an INR check; continued prescribing without any check; then warfarin prescription was discontinued. Pharmacist	Monitoring failure

			Chief Executive Cwm Taf University Health Board A GP Practice Primary Clinical Director, Aneurin Bevan University Health Board Consultant Psychiatrist, North Community Mental Health Team			nonetheless supplied it; the patient died from gut haemorrhage	
93.	96 F	2016-0080	Chief Executive Officer, Stockport NHS Foundation Trust	Co-trimoxazole Teicoplanin	Antibiotics	Knee replacement about 2000. The knee became septic. No antibiotics were given for 48h. Then he was treated with co-trimoxazole. He was also prescribed teicoplanin (but this was omitted for 24h). He developed disseminated intravascular coagulation and died	Omission of necessary treatment (teicoplanin) ADR to prescribed medicines (co-timoxazole)
94.	M	2015-0437	Medical Director, Barts Health	Heparin	Anticoagulants	Unwitnessed fall; fractured hip and shoulder, confused with heparin.	ADR to prescribed medicines
95.	37 M	2016-0249	Practice Manager, GP Medical Centre;	Opioids Codeine Methadone	Opioids Hypnotics and sedatives	Drank alcohol and developed bronchopneumonia. In hospital,	Interaction—ADR to prescribed medicines

			Medical Director NHS England Medical Director, Greater Manchester	Clonazepam		and given naloxone. Self-discharged Given daily meds 'Although the prescription was stopped, it was started again in error' (clonazepam).' Found dead in bed	Poor systems (erroneous reinstatement of prescription)
96.	M	2016-0245	Governor, Leicester Prison	Cannabinoid	Drug of Abuse	Hanging in prison cell – 'low traces of Mamba' — unclear of relevance of Mamba. Inadequate observation. Inappropriate delay in help.	Monitoring failure Delayed treatment (of hanging)
97.	F	2016-0049	Chief Executive, Sainsbury's Chief Executive Oadby & Wigston Borough Council Chief Executive, HSE	Warfarin	Anticoagulants	On warfarin; fell when lift doors opened without warning; hit head. Suffered a large subdural bleed and died	ADR to prescribed medicines (action relates to door opening)
98.	87 F	2015-0169	Newgate Medical Group	Warfarin	Anticoagulants	Atrial fibrillation. INR 8.0, Fall while the INR was high, in spite of vitamin K, developed intracerebral haemorrhage, and died.	Monitoring failure: poor systems (prescribing and monitoring warfarin treatment)
99.	M	2016-0308	MHRA	Hyoscine butylbromide		Given hyoscine butylbromide during routine colonoscopy. Sudden deterioration. Cardiac arrest. Died	ADR to prescribed medicines Poor awareness of rare ADRs

						Risk of ADR not widely known. Summary of Product Characteristics is unsatisfactory. Requires amendment.	Susceptible patient (ischaemic heart disease – undiagnosed)

Abbreviations: A&E – Accident and Emergency Department; ADR – adverse drug reaction; DVLA – Driver and Vehicle Licensing Authority; GP – General Practitioner; HMP – Her Majesty's Prison; HSE – Health & Safety Executive; INR – international normalized ratio; LMWH – low molecular weight heparin; MCCA – multi-compartment compliance aid; MDMA = 3,4-methylenedioxymethamphetamine; MHRA – Medicines and Healthcare products Regulatory Agency; MRSA – methicillin-resistant *Staphylococcus aureus*; NHS 111 – National Health Service telephone urgent and emergency care service; NICE – National Institute for Health and Care Excellence.

Preventing future deaths from medicines: responses to Coroners' concerns in England and Wales. Drug Safety. Robin E Ferner, Tohfa J Ahmad, Zainab Babatunde, Anthony R Cox. Corresponding author Robin E Ferner, Email: r.e.ferner@bham.ac.uk

Supplementary Table 2. Table showing the number of organizations required to respond to the Coroners letter to prevent future death, the number of organisations contacted for information and their response.

Judiciary website number	Number of entities required to respond to Coroner's report	Number of responses posted on-line at the start of the study	Number of addressees required to respond who were sent FoIs	Total number sent FoIs or requests for data	Number who provided data in response to our request	Number who responded but did not provide data	Number of people who failed to respond	NOTES
2016-0071	1	0	1	1	0	0	1	
2016-0183	1	0	1	1	1	0	0	
2015-0451	1	0	1	1	0	1	0	NHS England provided general information, nothing specific on this case
2015-0229	3	0	3	3	3	0	0	3 FOI to the same hospital (different individuals), 1 response received but response covered all 3 individuals
2015-0381	2	0	2	2	0	2	0	Cambian group -private- did not provide data, Guys cited court exemption
2015-0413	2	0	2	2	2	0	0	Addressed to two departments in the same hospital, received response that covered both departments
2016-0238	3	0	3	3	2	1	0	G4S did not provide data
2016-0208	2	2	0	0	0	0	0	
2015-	1	0	1	1	1	0	0	

0394								
2015-0468	4	0	4	4	4	0	0	One response by MoJ covered all 4; Birmingham Prison ignored our individual request, Birmingham community gave partial response but cited exemption and did not provide copy of their individual response
2015-0255	3	0	3	3	1	2	2	UHL exemption cited, NHS England gave general response; no details regarding this case, East Midlands ambulance gave full detailed response
2015-0301	1	0	1	1	1	0	0	
2015-0438	1	0	1	1	0	0	0	
2016-0013	1	0	1	1	0	1	0	Exemption cited then did not respond
2015-0463	1	0	1	1	0	0	1	Teva is private company
2015-0196	1	1	0	0	0	0	0	
2016-0147	1	0	1	2	1	1	0	Two addressees, but only one required to respond
2015-0170	1	0	1	1	1	0	0	
2015-0404	1	0	1	1	1	0	0	
2016-0222	1	0	1	1	0	1	0	
2016-0143	1	1	0	0	0	0	0	
2016-0239	1	1	0	0	0	0	0	

2015-0410	1	0	1	1	1	0	0	
2015-0402	1	0	1	1	1	0	0	
2016-0058	3	0	3	3	1	2	0	Nottinghamshire health responded. CRI is private and did not provide detailed information. NHS England provided general information not specific to the case
2015-0289	2	1	2	1	0	2	0	Posted response by DoH refers to NHS England response. NHS England provided general information, nothing specific on this case, DoH requested more time but did not respond
2016-0252	3	3	0	0	0	0	0	
2015-0273	1	0	1	1	1	0	0	
2016-0173	2	1	1	1	0	1	0	
2015-0372	3	0	3	3	0	2	1	Home Office provided general advice over the phone but did not give specific details of this case. ACMD responded that they received PFD for information only and not required to respond
2015-0453	2	0	2	2	1	0	1	
2016-0117	1	0	1	1	1	0	0	
2016-0057	1	0	1	1	1	0	0	
2015-0264	1	0	1	1	1	0	0	
2016-0078	2	0	2	6	1	5	0	Two addressees, and four further public body recipients

2015-0419	1	0	1	1	0	0	1	
2016-0248	1	1	0	0	0	0	0	
2015-0192	1	0	1	1	0	1	0	
2015-0161	2	0	2	2	1	1	0	One response online now
2016-0115	1	0	1	2	1	1	0	Copy of Coroner's report sent to Care Quality Commission
2016-0131	2	0	2	2	2	0	0	
2015-0317	2	0	2	3	0	2	1	One individual with two roles sent FoI twice
2016-0047	1	0	1	1	1	0	0	
2015-0254	1	0	1	1	1	0	0	
2016-0163	3	2	1	1	0	1	0	Chief Fire Officers not required to respond
2015-0392	1	0	1	1	1	0	0	
2015-0195	1	1	1	0	0	0	0	Coroner's report did not name addressee
2015-0221	1	0	1	1	0	1	0	Health board did not provide detailed response, but response was published online during study
2016-0228	1	1	0	1	0	1	0	
2016-0111	1	0	1	1	1	0	0	
2015-0377	1	0	1	1	1	0	0	Response also now online

2015-0414	6	0	6	7	4	0	3	Two Coroner's reports on the same case; a further Trust also named, but not required to respond
2015-0191	1	1	0	0	0	0	0	
2015-0217	1	0	1	1	0	0	1	response now online
2015-0282	2	0	2	2	0	2	0	Two people at the same hospital, exemption cited - future publication
2016-0174	1	0	1	1	1	0	0	
2016-0062	1	0	1	1	1	0	0	
2016-0254	4	0	4	4	3	1	0	
2015-0247	1	0	1	1	0	0	0	
2016-0156	1	0	1	3	0	1	2	Two further entities named, but not required to respond
2016-0171	1	1	0	1	0	1	0	
2015-0237	1	0	1	1	0	1	0	Exemption cited - available by other means; did not respond to follow up emails
2015-0231	1	0	1	1	0	1	0	MHRA exemption cited- future publication
2016-0295	1	0	1	1	0	1	0	ACMD stated they do not respond directly to Coroners- Home Office minister does this, Home Office did not provide details.
2016-0010	2	2	0	1	0	1	0	Response online was a joint response, ACMD received copy for information only
2015-0310	2	0	2	3	0	3	0	A further entity named, but not required to respond

2016-0224	1	1	0	0	0	0	0	
2015-0177	4	3	1	2	0	0	2	
2015-0444	1	0	1	1	1	0	0	
2015-0400	1	0	1	2	0	2	0	A further entity named, but not required to respond
2016-0014	3	0	3	3	3	0	0	Takeda gave information via phone; Macmillan stated they do not employ nurses themselves, it is the trust responsibility; GP surgery gave detailed information
2016-0246	1	1	0	0	0	0	0	
2015-0295	3	0	3	3	2	1	0	MHRA did not respond
2015-0210	2	0	2	3	0	2	1	Copy of Coroner's report sent to Care Quality Commission
2015-0423	1	0	1	4	0	3	1	The care home did not provide copy of their detailed response; copies of the Coroner's report were sent to an NHS Trust, a Clinical Commissioning Group, and a Town Council.
2016-0197	1	0	1	1	1	0	0	
2015-0241	1	0	1	1	1	0	0	
2015-0474	3	3	0	0	0	0	0	
2016-0017	1	0	1	2	1	1	0	Copy of Coroner's report sent to Care Quality Commission
2016-0242	1	0	1	1	0	1	0	

2016-0075	1	0	1	3	1	1	0	Copy of Coroner's report sent to Care Quality Commission and a Director of Public Health
2015-0298	2	0	2	2	2	0	0	
2015-0382	2	0	2	2	2	0	0	
2016-0042	1	0	1	1	0	1	0	
2015-0199	2	2	0	0	0	0	0	Joint response posted online
2016-0123	1	1	0	0	0	0	0	
2016-0081	1	0	1	3	1	2	0	Coroner's report also sent to NHS England and an NHS Trust
2016-0176	1	0	1	2	1	1	0	Coroner's report also sent to an NHS Trust
2016-0096	5	0	5	5	2	0	3	
2015-0309	1	0	1	1	1	0	0	
2016-0079	2	0	2	3	0	0	3	
2015-0262	1	0	1	5	3	1	1	Five addressees but matters of concern are addressed only to the GP practice
2016-0080	1	0	1	2	1	1	0	
2015-0437	1	0	1	1	1	0	0	
2016-0249	3	2	0	0	0	0	0	Published response is joint response by NHS England and NHS Area (Manchester), health centre is an addressee but FOI was not sent to them

2016-0245	1	1	0	0	0	0	0	
2016-0049	3	0	3	3	3	0	0	
2015-0169	1	0	1	1	1	0	0	
2016-0308	1	1	0	0	0	0	0	
TOTALS	**159**	**34**	**126**	**156**	**73**	**58**	**25**	

FoI = Request under Freedom of Information Act 2000

AUTHOR DECLARATION FORM

At submission, **EVERY AUTHOR** listed in the manuscript must **READ** and **COMPLETE** the following statements on: (A) Authorship Responsibility, (B) Authorship Criteria, (C) Authorship Contribution, (D) Funding Disclosures, (E) Contributor Disclosures/Acknowledgments, and (F) Conflicts of Interest Disclosures.

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Journal name: DRUG SAFETY Corresponding author: R.E FERNER

Manuscript title: Preventing Future deaths from medicines: responses to Coroners' concerns in England and Wales

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